



Eldora Ellison  
Helene Carlson  
Sterne, Kessler, Goldstein & Fox PLLC  
1100 New York Ave., NW  
Washington, DC 20005

In Re: Patent Term Extension  
Application for U.S. Patent No. 7,008,765  
Filed: April 11, 2012

mailed  
JUL 31 2012  
DPLA

### NOTICE OF INFORMALITIES

The above-identified application for patent term extension (PTE application) has been accorded a filing date of April 11, 2012, however, certain regulatory requirements have not been fulfilled.

- (1) The PTE application was not filed by a party recognized under 37 C.F.R. 1.730.
- (2) Section 1.740(a)(9) of title 37 of the Code of Federal Regulations requires,

A statement that the patent claims the approved product, or a method of using or manufacturing the approved product, and a showing which lists each applicable patent claim and demonstrates the manner in which at least one such patent claim reads on:

- (i) The approved product, if the listed claims include any claim to the approved product;
- (ii) The method of using the approved product, if the listed claims include any claim to the method of using the approved product; and
- (iii) The method of manufacturing the approved product, if the listed claims include any claim to the method of manufacturing the approved product. . . .

See 37 C.F.R. 1.740(a)(9)(i)-(iii).

First, 37 C.F.R. 1.730 requires that an application for patent term extension be filed by "the owner of record or its agent. . . ." 37 C.F.R. 1.730(a). When an agent of the patent owner is filing the application for patent term extension, then the signature requirements must fulfill 37 C.F.R. 1.730(c). Here, the signature on the submission of the application is from an agent of the owner. However, R. William Bowen, Jr. is not a registered practitioner acting on behalf of the agent of the patent owner. To properly comply with 37 C.F.R. 1.730(c), Applicant must furnish a duplicate application properly signed or ratify the application already on file. This means a single properly signed copy.

Second, the manner of showing how the patent claims the product, in reference of claim 6, solely indicates that the approved product contains "an isolated nucleic acid molecule. . . ." and repeats verbatim the language of claim 6 without any specificity as to which of the recited alternate sequences of claim 6 are present in the approved product. While it is understood, from page 4 of the PTE application, that the sequence information regarding the molecules is proprietary

information of the Marketing Applicant, assessment of compliance with the applicable regulatory provisions of 37 C.F.R. 1.740-et seq. cannot be completed without such information. Applicant's attention is directed to MPEP § 724.02 which sets forth procedures for submission of proprietary information.

Applicant is given a TIME PERIOD of ONE (1) MONTH or THIRTY (30) DAYS from the mailing date of this notice, whichever is longer, to comply with the requirements enumerated above. Extensions of time under 37 C.F.R. 1.136(a) are not applicable to this time period.

Any correspondence from applicant with respect to this matter should be addressed as follows:

By mail: Assistant Commissioner for Patents  
Mail Stop Hatch-Waxman PTE  
P.O. Box 1450  
Alexandria, VA 22313-1450

By FAX: (571) 273-0100  
Attn: Office of Patent Legal Administration

Telephone inquiries related to this notice should be directed to the undersigned at (571) 272-7755.



Mary C. Till  
Senior Legal Advisor  
Office of Patent Legal Administration  
Office of the Deputy Commissioner  
for Patent Examination Policy

cc: Office of Regulatory Policy  
Food and Drug Administration  
10903 New Hampshire Ave., Bldg. 51, Rm. 6222  
Silver Spring, MD 20993-0002

RE: PROGENSA® (PCA3  
Assay)  
Docket No.: FDA-2012-E-

Attention: Beverly Friedman